UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,284	02/09/2004	Yuan Y. Lee	USP2270A-YYL	1138

30265 7590 03/06/2008

RAYMOND Y. CHAN
108 N. YNEZ AVE., SUITE 128
MONTEREY PARK, CA 91754

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
03/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,284	LEE, YUAN Y.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/14/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-39* is/are pending in the application.

4a) Of the above claim(s) *5-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

It is noted that Applicants filed a Request for Continued Examination (RCE) on December 14, 2007. However, 37 CFR 1.111 does not allow for filing an RCE prior to closure of prosecution. As indicated in the Notice of Improper Request for RCE mailed to applicant on December 26, 2007, the response filed concurrently with the RCE will be treated as an amendment submitted after a non-final Office action, but not as an RCE.

Claims 5-39 are pending in the application.

Claims 5-35 remain withdrawn from the merits as they are directed toward a non-elected invention.

Claims 36-39 were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 103

Claims 36-39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (US 5,741,491) in view of Yang et al. (2003).

Applicant's arguments as well as the amendments to the claims were fully considered, but not found persuasive.

Applicants have amended claim 39 in the following manner:

Claim 36 (currently amended): A herbal composition for treatment of a patient having diabetes mellitus, arthritis, and neuralgia, wherein said herbal composition comprises a predetermined quantity of Toona sinensis for exerting an effect of lowering blood glucose level and a predetermined quantity of Heracleum lanatum for posing anti-inflammatory effect on said patient, wherein said composition is interactively providing an elevated effect of treatment diabetes, arthritis and neuralgia:,
wherein said herbal composition is prepared by the steps of:
a) providing said predetermined quantity of Toona sinensis;
b) providing said predetermined quantity of Heracleum lanatum wherein said Toona sinensis and said Heracleum lanatum has a predetermined composition ratio by weight, wherein said Toona sinensis is fully immersed in six cups of water;
c) adding said Toona sinensis and said Heracleum lanatum to form an essential composition having a volume of two cups;
d) adding a predetermined volume of water to said essential composition to form a pre-heat mixture wherein said volume of water and said volume of said essential composition has a predetermined mixing ratio of 1:1; and
e) heating said pre-heat mixture under a predetermined temperature for a predetermined heating time to form an after-heat mixture, wherein said volume of water in step (b) and said final solution in step (c) has a ratio by volume of 3:1,
wherein said herbal composition is administered through a process of treatment for diabetes comprising the steps of:
providing a treatment plan having a predetermined number of days and a predetermined number of dosages of herbal composition with respect to each of said number of days; and
administering said number of dosages of herbal composition with respect to said number of days according to said treatment plan, wherein said herbal composition comprises a predetermined quantity of Toona sinensis, and said Toona sinensis is fully immersed in water.

Applicants initially reiterate the statute governing 35 USC 103(a) and asserts that the claimed composition is not obvious over the combination of Yang et al. and Jones (pp. 9-10, Remarks).

Specifically, Applicants argue that Yang et al. and Jones:

> [fail] to *anticipate* a herbal composition comprising a predetermined quantity of Toona sinensis for exerting an effect of lowering blood glucose level and a predetermined quantity of Hercleum lanatum for posing anti-inflammatory effect on said patient, wherein when the composition is prepared by the steps recited in (a) to (e), and that the composition is administered through the steps recited in the newly amended independent claim 36, the result for treating diabetes is unexpectedly good (p. 10, Remarks, emphasis added).

First, it is conceded that the combination of Yang et al. and Jones fail to anticipate the claimed invention, in that the outstanding rejection is based upon obviousness according to the provisions set forth by 35 USC 103(a) and not anticipation according to the provisions set forth by 35 USC 102(b).

However, the claimed invention remains obvious in view of the cited prior art references for the reasons which follow.

The differences between the claimed invention after applicant's amendments to the claims will be reestablished. In order to do so, the teachings of Jones (US 5,741,491) in view of Yang et al. (2003) will be reiterated below.

Jones (US 5,741,491) discloses a method for treating diabetes via administration of a water extract of *Hercacleum lanatum* along with a species of Populus (see Abstract for example). Jones explains that any part of the *H. lanatum* plant may be used such as the roots (see col. 2, lines 30-41 for example).

Yang et al. (2003) discovered that the water/alcohol extract of *Toona sinensis* leaves increased basal and insulin-stimulated glucose-uptake in 3T3-L1 adipocytes (see English Abstract).

The claims are now directed toward Product-by Process. It must be first indicated then, that examination of Product-by-process claims is governed by the guidelines set forth in MPEP § 2113:

> PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS
> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more

expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).
>The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)<

The relevant passage of the claim which recites the product-by-process is repeated below:

wherein said herbal composition is prepared by the steps of:
a) providing said predetermined quantity of Toona sinensis;
b) providing said predetermined quantity of Heracleum lanatum wherein said Toona sinensis and said Heracleum lanatum has a predetermined composition ratio by weight, wherein said Toona sinensis is fully immersed in six cups of water;
c) adding said Toona sinensis and said Heracleum lanatum to form an essential composition having a volume of two cups;
d) adding a predetermined volume of water to said essential composition to form a pre-heat mixture wherein said volume of water and said volume of said essential composition has a predetermined mixing ratio of 1:1; and
e) heating said pre-heat mixture under a predetermined temperature for a predetermined heating time to form an after-heat mixture, wherein said volume of water in step (b) and said final solution in step (c) has a ratio by volume of 3:1,

It is determined that the product resulting from the process according to the claimed invention will result in a water extract containing equal amounts of *Toona sinensis* and *H.lanatum* extracts (as the plant material is added to the water in equal proportions).

The administration steps following the product-by-process include the following:

wherein said herbal composition is administered through a process of treatment for diabetes comprising the steps of:

providing a treatment plan having a predetermined number of days and a predetermined number of dosages of herbal composition with respect to each of said number of days; and administering said number of dosages of herbal composition with respect to said number of days according to said treatment plan, wherein said herbal composition comprises a predetermined quantity of Toona sinensis, and said Toona sinensis is fully immersed in water.

These steps fail to impart any further physical distinctive properties to the herbal water extract and thus, do not add or subtract from the patentability (or non-patentability) of the claimed invention.

Thus, the differences between the claimed invention and that of the prior art are:

1) the prior art did not explicitly teach admixing extracts of *H.lanatum* and *T.sinensis*.

It must be noted that the Instant claims now require that the *T.sinensis* extract is a water extract, and not a water/alcohol extract as taught by Yang et al. However, while Yang et al. taught a water/alcohol extract, this extract is deemed to make obvious a water extract because the water/alcohol extract as disclosed by Yang et al. would inherently contain all of the water-soluble constituents extracted by water.

Further, although Jones discloses that a species of Populus was admixed with the extract of *H.lanatum*, it is noted that the claims state 'comprising' which is open language, thus allowing the incorporation of material besides *H. lanatum* and *T. sinensis*.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating diabetes/increasing glucose - uptake. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Applicant sets forth the requirements of establishing a prima facie case of obviousness:

"A prima facie case of obviousness requires setting forth (a)....(d)...[t]hese factors have not been appropriately applied in this case. In addition, when applying 35 USC 103, the following tenets of patent law must be adhered to: (a)....(d)" (pp. 10-11, Remarks).

In response, the Examiner indicates that the claimed invention has been considered as a whole, in light of the specification, and in light of the knowledge of the ordinary artisan at the time the invention was made. The prior art suggests the

desirability of the claimed invention because it was obvious to combine extracts which were known for the same purpose in order to form another composition for the same exact purpose. The ordinary artisan would have been motivated to do so to provide an additive effect on treating diabetes. The references were viewed without the benefit of hindsight vision in that each reference, prior to Invention was already known in the art for treating diabetes. The Examiner did not draw on any foresight found in the Instant specification to render this conclusion; as it was already clear from the prior art that each herb was known in the art for treating diabetes. Therefore, again, at the time the invention was made, it would have been desirable to combine *T. sinensis* leaves and *H. lanatum* roots at equal proportions in order to treat diabetes: ."[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742 (emphasis added).

Applicants argue that "Jones and Yang et al. fail to anticipate that the Toona sinensis is leaves of Toona sinensis and the Heracleum is roots of Heracleum lanatum..." (p. 11, Remarks). First, Applicants are once again arguing that the prior art does not anticipate the claimed invention while the outstanding rejection is made in view of the combination of references under 35 USC 103(a). Further, it has been firmly established in this, as well as previous Office actions that Jones specifically taught extraction of *H. lanatum* roots, and that Yang et al. teach extraction of *T. sinensis* leaves.

Applicants argue that "Jones and Yang et al. fail to anticipate that said quantity of Toona sinensis is not less than said quantity of Heracleum lanatum by weight, in addition... To reiterate from a previous Office action, it is true that Jones does not teach this aspect of the claimed invention, however, Applicant again is arguing the reference alone, wherein the rejection is made upon a combination of Jones in view of Yang et al. Although the prior art did not specifically teach that the quantity of Toona sinensis is 'not less than the quantity of Heracleum lanatum', one of ordinary skill in the art would have been motivated to combine the *T.sinensis* and *H.lanatum* in equal amounts to provide for an additive effect with regard to diabetes treatment. Equal amounts is 'not less than' the quantity of *H. lanatum*. In addition the MPEP further states: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. The ordinary artisan would have recognized that optimization of such parameters would have been advantageous for manufacturing products with varying affectivities (e.g.,

regular and extra-strength). [If]... there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007. It is deemed that the optimization of amounts of extracted herbal products of *H.lanataum* and *T.sinensis* would have been well within the purview of the ordinary artisan at the time the invention was made.

Applicant argues that the evidence submitted in the Appendix accompanying Applicants" most recent response is evidence of unexpected results. However, evidence comprising data in support of an unexpected result must be in the proper form of an Affidavit or Declaration and therefore is insufficient in order to provide any evidence of an unexpected result. It is further reminded that any extrinsic evidence submitted in support of an unexpected result must be commensurate in scope with the claimed invention. Because the Appendix is not in the proper form of a Declaration or Affidavit, the evidence therein fails to provide support for any unexpected result as alleged by Applicants.

The Supreme court has acknowledged that:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable varition..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's

> skill. **A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions**...(see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) (emphasis added)

The desirability of combining the herbal extracts was present in the art prior to Applicants' patent for Invention and has been keenly established on the record. Again, "It is not necessary that the prior art suggest the combination *to achieve the same advantage or result discovered by applicant*" "*The recitation of an additional advantage associated with doing what the prior art suggests does not lend patentability to an otherwise unpatentable invention.*" *In re Lintner*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) and In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990) (emphasis added). Further, , taking the disclosure as a whole into consideration, it does not appear that the combination of *T.sinensis* and *H. lanatum* provide for any unexpected results with regard to any new properties stemming from the mixture of the herbs such as a synergistic effect of treating diabetes. Further, the Specification explicitly teaches that *T.sinensis* was already a known antiinflammatory, analgesic and anti-arthritic medicine. Therefore, in this respect, it is not conclusive that a treatment of neuralgia (facial pain) is an 'advantage' of the combination of the herbal ingredients because *T.sinensis* was already a known analgesic as admitted by Applicant.

> ...**the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention based upon the predictability of each plant extract to be advantageous in treating blood glucose levels. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the references.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action (i.e., any new reasons presented for rendering the claimed invention obvious were brought about due to Applicants' amendments to the claimed invention). Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith

Primary Examiner
Art Unit 1655

/Patricia Leith/
Primary Examiner, Art Unit 1655
February 27, 2008